

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
9 August 2007 (09.08.2007)

PCT

(10) International Publication Number
WO 2007/090009 A1

(51) International Patent Classification:

A61B 17/70 (2006.01)

(21) International Application Number:

PCT/US2007/060905

(22) International Filing Date: 23 January 2007 (23.01.2007)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

11/341,200

27 January 2006 (27.01.2006)

US

(71) Applicant (for all designated States except US): **WAR-SAW ORTHOPEDIC, INC.** [US/US]; 2500 Silveus Crossing, Warsaw, Indiana 46581 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **TRIEU, Hai H.** [US/US]; 1323 Graystone Lane, Cordova, Tennessee 38016 (US).

(74) Agents: **JOHNSON, Noreen, C.** et al.; 710 Medtronic Parkway MS LC340, Minneapolis, Minnesota 55432 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

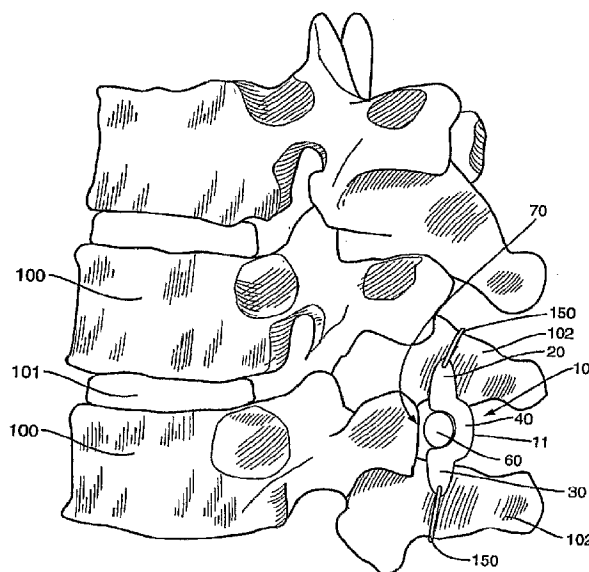
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERSPINOUS DEVICES AND METHODS OF USE



(57) Abstract: Devices and methods for spacing the spinous processes of adjacent vertebral members. In one embodiment, the device includes first and second sections and an intermediate section that together form an interior section. An elastic member may be positioned within the interior section. The elastic member may have a variety of orientations, sizes, shapes, densities, modulus of elasticity, and other material properties depending upon the desired displacement between the first and second sections. The intermediate section in combination with the elastic member may be deformed during this movement and thereby exert a force to stabilize the vertebral members.

WO 2007/090009 A1

INTERSPINOUS DEVICES AND METHODS OF USE

Background

The present application is directed to devices and methods for stabilizing vertebral members, and more particularly, to interspinous devices positioned between the spinous processes of vertebral members.

Vertebral members comprise a body, pedicles, laminae, and processes. The body has an hourglass shape with a thinner middle section and wider ends, and include sections on the inferior and superior ends. Intervertebral discs are positioned between the bodies of adjacent vertebral members to permit flexion, extension, lateral bending, and rotation.

The pedicles are two short rounded members that extend posteriorly from the body, and the laminae are two flattened members that extend medially from the pedicles. The processes are projections that serve as insertion points for the ligaments and tendons. The processes include the articular processes, transverse processes, and the spinous process.

The spinous process is a single member that extends posteriorly from the junction of the two lamina. The spinous process acts as a lever to effect motion of the vertebral member.

Various conditions may lead to damage of the intervertebral discs and/or the vertebral members. The damage may result from a variety of causes including a specific event such as trauma, a degenerative condition, a tumor, or infection. Damage to the intervertebral discs and vertebral members can lead to pain, neurological deficit, and/or loss of motion.

One method of correcting the damage is insertion of a device between the spinous processes of adjacent vertebral members. The device may reduce or eliminate the pain and neurological deficit, and increase the range of motion.

Summary

The present application is directed to devices and methods for spacing the spinous processes of adjacent vertebral members. In one embodiment, the device includes first and second sections and an intermediate section that together form an interior section. An

elastic member may be positioned within the interior section. The elastic member may have a variety of orientations, sizes, shapes, densities, modulus of elasticity, and other material properties depending upon the desired displacement between the first and second sections.

In use according to one embodiment, the device may assume a first shape when the vertebral members are aligned, such as when the patient is standing erect or in a prone position. This first shape may include the first and second sections spaced a first distance apart. During movement of the vertebral members, the device may be placed in compression or tension. The intermediate section in combination with the elastic member may be deformed during this movement and thereby exert a force to stabilize the vertebral members.

Brief Description of the Drawings

Figure 1 is a side view of a device positioned between adjacent spinous processes according to one embodiment.

Figure 2 is a side schematic view of a body according to one embodiment.

Figure 3 is a side schematic view of a body according to one embodiment.

Figure 4 is a side schematic view of a device according to one embodiment.

Figure 5 is a rear view of a device according to one embodiment.

Figure 6 is a rear view of a device according to one embodiment.

Figure 7 is a perspective view of a body according to one embodiment.

Figure 8 is a rear view of a device according to one embodiment.

Figure 9 is a rear view of a device according to one embodiment.

Figures 10A-H are side schematic views of bodies according to various embodiments.

Figure 11 is a side view of a device positioned between adjacent spinous processes according to one embodiment.

Figure 12 is a perspective view of a body according to one embodiment.

Figures 13A-F are schematic cross section views of elastic members according to various embodiments.

Figure 14 is a schematic cross section view of a device according to one embodiment.

Figure 15 is a schematic cross section view of a device according to one embodiment.

Figure 16 is a schematic cross section view of a device according to one embodiment. Figure 17 is a schematic cross section view of a device according to one embodiment. Figure 18 is a schematic cross section view of a device according to one embodiment. Figure 19 is a schematic cross section view of a device according to one embodiment. Figure 20 is a schematic cross section view of a device according to one embodiment. Figure 21A-21B are schematic cross section views of a device according to one embodiment.

Figure 22A is a side schematic view of a device in a neutral configuration according to one embodiment.

Figure 22B is a side schematic view of a device with the bases moved outward according to one embodiment.

Figure 23 is a side schematic view of a device with a tether according to one embodiment.

Figure 24 is a rear or front schematic view of a device with a tether according to one embodiment.

Figure 25 is a side schematic view of a device with a tether according to one embodiment.

Figure 26 is a rear or front schematic view of a device with a tether according to one embodiment.

Detailed Description

The present application is directed to devices and methods for spacing apart spinous processes of adjacent vertebral members. The device may include a body sized to fit between the adjacent spinous processes. The body may include upper and lower sections and an intermediate section that together form an interior section. An elastic member is positioned within the interior section. The elastic member may have a variety of orientations, sizes, shapes, densities, modulus of elasticity, and other material properties depending upon the desired displacement between the first and second sections. The elastic member and/or the intermediate section may be elastically flexible to exert a stabilizing force during movement of the vertebral members.

Figure 1 illustrates one embodiment of a device 10 positioned between the spinous processes 102 of adjacent vertebral members 100. The device 10 in this embodiment includes a body 11 comprising an upper section 20, a lower section 30, and an

intermediate section 40. Upper and lower sections 20, 30 are each shaped and sized to contact one of the spinous processes 102. Intermediate section 40 spaces apart the upper and lower sections 20, 30 forming an interior section 70. An elastic member 60 is positioned within the interior section 70. The elastic member 60 and intermediate section 40 are elastically flexible to stabilize the vertebral members 100.

In one embodiment, the intermediate section 40 and elastic member 60 provide variable resistance during movement of the vertebral members 100. The resistance may provide dynamic stabilization during a normal range of motion from the neutral position during flexion, extension, lateral bending, and rotation. The stiffness of the intermediate section 40 and elastic member 60 may further limit the range of motion beyond a predetermined amount.

Body 11 comprises the upper and lower sections 20, 30 and the intermediate section 40. In one embodiment such as illustrated in Figure 1, the body 11 is constructed of a single member having a folded configuration. In other embodiments, body 11 is constructed of two or more different members. Figure 2 illustrates one embodiment with the intermediate section 40 constructed of a separate piece that is attached to the sections 20, 30. Upper section 20 is attached to the member 18 with one or more fasteners 90. Embodiments of fasteners 90 may include rivets, pins, screws, etc. Lower section 30 is attached to the member 18 in another manner, such as with adhesives, welding, brazing, etc. Figure 3 illustrates another embodiment with the intermediate section 40 constructed of two separate members 18a, 18b. In this embodiment, first member 18a is integral with section 20, and second member 18b is integral with section 30. Members 18a, 18b are connected together in a manner as described above. Body 11 may be constructed of a variety of materials including metals, polymers, ceramics, and combinations thereof. Examples of metals include titanium, titanium alloys such as nickel-titanium, stainless steel, and cobalt chromium. Examples of polymers include silicone, silicone-polyurethane copolymer, polyolefin rubber, PEEK, PEEK-carbon composites, polyimide, polyetherimide, polyurethane, and combinations thereof. Examples of polyurethanes include thermoplastic polyurethanes, aliphatic polyurethanes, segmented polyurethanes, hydrophilic polyurethanes, polyether-urethane, polycarbonate-urethane, silicone polyetherurethane, polyvinyl alcohol hydrogel, polyacrylamide hydrogel, and polyacrylic hydrogel. Examples of ceramics include calcium phosphate, hydroxyapatite, HAPCP,

alumina, and zirconium. Various shapes, sizes, materials, and constructions for interspinous spacers are disclosed in U.S. Patent Application Serial No. 10/851,889 herein incorporated by reference.

Sections 20, 30 are shaped to contact the spinous processes 102 of the vertebral members 100. In one embodiment as illustrated in Figures 4 and 5, upper section 20 includes a base 24 and upwardly-extending first and second arms 21, 22. A gap 23 is formed between the arms 21, 22 and the base 24 and is sized to receive the spinous process 102. In this embodiment, the lower section 30 has substantially the same shape and size with a base 34 and upwardly-extending first and second arms 31, 32. A gap 33 is formed between the arms 31, 32 and the base 34 and is sized to receive the spinous process 102.

In one embodiment as illustrated in Figure 5, the arms 21, 22 of the upper section 20 are substantially the same as the arms 31, 32 of the lower section 30. In other embodiments, arms 21, 22 have different heights than arms 31, 32. Figure 6 illustrates one embodiment with arms 21, 22 have a lesser height than arms 31, 32. Arms may be substantially parallel as illustrated by the arms 21, 22 and 31, 32 of Figure 5. In another embodiment, arms are non-parallel as illustrated by arms 31, 32 in Figure 6. Arms may further have the same or different thicknesses.

In one embodiment, upper and lower sections 20, 30 are constructed of flexible materials that allow for the arms 21, 22, 31, 32 to elastically flex to accommodate the spinous processes. When the body 11 is in a neutral configuration with no external forces acting on it, gaps 23, 33 may be the same size, or may have different sizes. Bases 24, 34 may have the same lengths such as the embodiment illustrated in Figures 2 and 3. In another embodiment, bases 24, 34 have different lengths as illustrated in Figure 7. One embodiment illustrated in Figure 7 includes the upper section 20 having a split configuration. Gap 23 extends between the arms 21, 22, and a length of the base 24. In one embodiment, the two sections of the base 24 are spaced away a distance for each to contact and support the spinous process 102. In one embodiment, lower section 30 may be formed as a single section (i.e., without a gap 33). In one embodiment, base 34 may have an extended length with the single arm 31 positioned on a posterior edge of the spinous process 102.

Bases 24, 34 may be positioned at a variety of relative angular positions when no external forces are applied to the body 11. In one embodiment, bases 24, 34 are substantially parallel. In another embodiment, the bases 24, 34 angle outward from the intermediate section 40 such that a height of the interior section 70 is less near the intermediate section 40 and increases towards the ends of the bases 24, 34. In another embodiment, bases 24, 34 angle inward as they extend from the intermediate section 40. Arms 21, 22, 31, 32 may be positioned at a variety of locations relative to the respective bases 24, 34. In one embodiment as illustrated in Figures 2 and 3, arms 21, 31 are positioned at the ends of the bases 24, 34 away from the intermediate section 40. In another embodiment as illustrated in Figure 11, arms 22, 32 are positioned towards the intermediate section 40 and away from the ends of the bases. In one embodiment, the arms of each base (e.g., arms 21, 22) are positioned at the same location relative to the intermediate section 40. In another embodiment, arms are positioned at different relative locations from the intermediate section 40.

Intermediate section 40 extends between the sections 20, 30 and provides resistance to movement of the sections 20, 30. Intermediate section 40 may have a variety of shapes. In one embodiment as illustrated in Figure 14, intermediate section 40 has substantially planar upper and lower sections. In other embodiments, intermediate section 40 has a curved shape as illustrated in Figure 4. In various other embodiments, intermediate section 40 has a combination of planar and curved shapes. The width of the intermediate section 40 may be substantially the same or different as one or both bases 24, 34. In one embodiment illustrated in Figure 8, the width of the intermediate section 40 is less than the sections 20, 30. The narrower width may be centered along a centerline of the body 11, or may be off-center. Figure 5 illustrates an embodiment with the intermediate section 40 having substantially the same width as the sections 20, 30. The thickness of the intermediate section 40 may be the same or different as one or both sections 20, 30. In one embodiment as illustrated in Figure 9, intermediate section 40 comprises two separate spaced-apart members 18a, 18b. An opening 41 may be formed between the members 18a, 18b.

In some embodiments, intermediate section 40 is constructed from a single member 18. Figures 10A and 10B illustrate embodiments with the intermediate section 40

having a curved shape. Figures 10C, 10D, and 10E illustrate embodiments having an intermediate section 40 comprised of planar and curved sections.

Embodiments of the intermediate section 40 may include multiple members 18. Figure 10F illustrates an embodiment with a curved first support member 18a and a second support member 18b. Figures 10G and 10H illustrate embodiments with first and second members 18a, 18b each including curved and planar sections. In embodiments having multiple members 18, members 18 may be constructed in a unitary fashion, or from multiple different members fastened together.

Support members 18 may also have an overlapping configuration. The overlap may be in a horizontal direction, vertical direction, or both. Member 18 of Figure 10A and members 18a and 18b of Figure 10G illustrate embodiments having vertical overlap with multiple sections of the member 18 being in overlap. Figures 10B, 10C, 10D, and 10E also include vertical overlap. Figures 10D and 10E illustrate embodiments of horizontal overlap with members 18a, 18b being horizontally positioned. Some embodiments feature both horizontal and vertical overlap. Intermediate sections 40 comprising multiple members 18 include horizontal overlap due to the construction. Each of the members 18 may themselves include horizontal and/or vertical overlap.

In one embodiment as illustrated in Figure 1, intermediate section 40 is positioned on a posterior side of the body 11. An opening into the interior section 70 faces in an anterior direction. In another embodiment as illustrated in Figure 11, the intermediate section 40 is positioned on an anterior side of the body 11 with the opening into the interior section 70 facing in the posterior direction. Figure 12 illustrates another embodiment with a more enclosed interior section 70. Intermediate section 40 includes members 18a, 18b that extend from the bases 24, 34 around the posterior and anterior sides of the interior section 70. The members 18a, 18b may have a variety of shapes and constructions as described above. In the embodiments of Figures 1, 11, and 12, the lateral sides of the interior section 70 are open. In other embodiments, one or both lateral sides may be closed.

Elastic member 60 is positioned within the interior space 14 and has a stiffness to provide resistance and resist movement of the sections 20, 30. The elastic member 60 shares the load applied to the device and may prevent fatigue failure of the intermediate

section 40. The elastic member 60 may impose a substantially linear or non-linear resistance to resist movement of the sections 20, 30.

Elastic member 60 may be constructed of a variety of different materials. Member 60 may be resilient and change shape during movement of the sections 20, 30. Examples of such materials include elastic or rubbery polymers, hydrogels or other hydrophilic polymers, or composites thereof. Particularly suitable elastomers include silicone, polyurethane, copolymers of silicone and polyurethane, polyolefins, such as polyisobutylene and polyisoprene, neoprene, nitrile, vulcanized rubber and combinations thereof. Examples of polyurethanes include thermoplastic polyurethanes, aliphatic polyurethanes, segmented polyurethanes, hydrophilic polyurethanes, polyether-urethane, polycarbonate-urethane and silicone polyetherurethane. Other suitable hydrophilic polymers include polyvinyl alcohol hydrogel, polyacrylamide hydrogel, polyacrylic hydrogel, poly(N-vinyl-2-pyrrolidone hydrogel, polyhydroxyethyl methacrylate hydrogel, and naturally occurring materials such as collagen and polysaccharides, such as hyaluronic acid and cross-linked carboxyl-containing polysaccharides, and combinations thereof.

Elastic member 60 may be connected to the body 11, or may be freely positioned within the interior section 70. In one embodiment, elastic member 60 is connected to one or more of the sections 20, 30 and intermediate section 40. The elastic member 60 may be connected with mechanical fasteners such as screws, pins, rivets, etc. In another embodiment, elastic member 60 is connected to the body 11 with an adhesive. In one embodiment, the inner edges of one or more of the sections 20, 30 and intermediate section 40 include a roughened surface, ridges, teeth, etc. to maintain the position of the elastic member 60. In one embodiment, the elastic member 60 has a shape that attaches to one or both of the sections 20, 30. In a specific embodiment, elastic member 60 includes a dovetail recess that attaches with an extension that extends from the body 11.

When connected to both endplates 11, 12, the elastic member 60 provides resistance to both inward and outward movement. During inward movement of the endplates 11, 12, elastic member 60 is compressed and provides a resistance to the inward movement. During outward movement of the endplates 11, 12, the elastic member 20 is placed in tension to provide resistance. In one embodiment, the elastic member 20 is placed in compression during extension of the vertebral members and placed in tension during flexion.

In one embodiment with the elastic member 60 connected to only one or neither endplate 11 or 12, the elastic member 60 provides resistance to inward movement. The elastic member 60 may not be placed in tension during outward movement and the resistance to this movement is limited to the intermediate section 40.

In various embodiments, elastic member 60 is constructed from a single member as illustrated in Figures 13A-13D. Figure 13A illustrates one embodiment having an elastic member 60 with a substantially rectangular shape. Figure 13B illustrates a substantially C-shaped elastic member 60 with the base facing away from the support member 18. Figure 13C illustrates an elastic member 60 having a rectangular first surface that contacts the section 30 and four planar sidewalls that taper upwards. Figure 13D illustrates an embodiment having an irregular, non-symmetrical shape.

Elastic member 60 may further include two or more separate members. The separate members may have the same construction, or may be constructed of different materials each having a different stiffness. Figure 13E illustrates an embodiment having three separate elastic members 60a, 60b, 60c. Each elastic member 60a, 60b, 60c is independent and has a substantially circular shape that may be cylindrical, spherical, or conical. Figure 13F illustrates an embodiment having a first elastic member 60a that extends around a second elastic member 60b. In one embodiment, elastic members 60a, 60b are connected together.

In a neutral condition with no external forces on the body 11, the elastic member 60 may have a variety of heights H. In one embodiment, the height H is sized for the member 20 to extend between and contact both sections 20, 30. In one embodiment, the height H may be substantially the same throughout the elastic member 60. In other embodiments as illustrated in Figures 14 and 15, the height H may vary along the elastic member 60.

Figure 14 includes elastic member 60 having a height that decreases away from the support member 18, and Figure 15 includes the elastic member 60 having a height that increases away from the support member 18.

The device 10 may provide a variable resistance to deformation. The variable resistance may cause less resistance to initial amounts of vertebral movement, but apply greater forces to reduce larger vertebral movements. By way of example, the device 10 may be designed to provide little resistance during an initial amount of movement of the

sections 20, 30. Larger amounts of resistance may be applied to the vertebral members when the sections 20, 30 move beyond the initial amount. In some embodiments, the stiffness of the elastic member 60 and intermediate section 40 increases with additional amounts of movement. The amount of resistance applied by each member increases the further they move away from the original, first position.

Variable resistance to inward movement may also result from the height of the elastic member 60. In one embodiment, the height H is less than the height of the interior section 70 (i.e., the member 60 does not contact both sections 20, 30). The resistance to the initial movement of the sections 20, 30 is isolated to the intermediate section 40. The elastic member 60 does not affect the stiffness until it is contacted by both sections 20, 30 and begins to elastically deform. In one embodiment, deformation is limited to the intermediate section 40 during an amount of initial section movement. Movement beyond this initial amount causes the sections 20, 30 to begin deforming the elastic member 60 in addition to continued deformation of the intermediate section 40 resulting in greater stiffness of the device and more resistance to additional movement.

The shape and size of the elastic member 60 may further cause variable resistance to deformation. Greater amounts of contact between the sections 20, 30 and the elastic member 60 may result in greater amounts of resistance. By way of example using the embodiments of Figures 14 and 15, the peaked shapes of the elastic members 20 provides less resistance during initial amounts of inward movement of the sections 20, 30. Additional inward movement of the sections 20, 30 results in deformation of larger amounts of the elastic member 60 resulting in greater resistance.

Variable resistance may also be provided by multiple elastic elements. Figure 16 illustrates an embodiment having two separate elastic members 60a and 60b. During inward movement of the sections 20, 30, the inner elastic member 60a is initially contacted thus causing a first amount of resistance. The second elastic member 60b is not contacted by the section 20 until the sections 20, 30 are compressed beyond a predetermined amount. This compression then causes the elastic member 60b to deform resulting in additional amounts of resistance. In this embodiment, elastic members 60a, 60b may have the same or different stiffnesses.

Figure 17 illustrates an embodiment having a single elastic member 60 constructed of first and second materials 78, 79 having a different stiffness. Initial compression of the

sections 20, 30 causes deformation of the first material 78 resulting in a first resistance. Additional compression causes deformation of the first and second materials 78, 79 which together provide additional resistance.

Figures 22A and 22B illustrate another embodiment having first and second members 60a, 60b positioned between the bases 24, 34. As illustrated in Figure 22A, member 60b has a greater length and is in a slackened configuration when the device is in a neutral orientation with no external forces. An initial outward movement of the bases 24, 34 is resisted initially by the first member 60a and the intermediate section 40. As the bases 24, 34 move outward, member 60b is pulled tight. Movement beyond this amount causes the member 60b to be stretched and resist to further movement is opposed by first and second members 60a, 60b and the intermediate section 40. Members 60a, 60b may be constructed of the same or different materials. In one embodiment, member 60b is constructed of a inelastic material and acts as a limiter to control the extent of outward movement. The bases 24, 34 may be moved apart an amount until the member 60b is pulled tight. The inelastic nature of the member 60b then prevents further outward movement of the bases 24, 34 beyond this amount.

Elastic member 60 may fill varying amounts of the interior section 70. In one embodiment, member 60 fills a limited amount of the interior section 70. In another embodiment as illustrated in Figures 18 and 19, elastic members 60 substantially fill the entirety of the interior section 70. In the embodiments of Figures 18 and 19, voids 77 are positioned within the elastic member 60. In one embodiment, voids have a specific shape and size to control the supporting abilities of the elastic member 60. Voids 77 may be substantially free of material, or may be filled with a material that is different than that of the elastic member 60. As illustrated in Figure 18, voids 77 may be positioned within the interior of the elastic member 60, or may be positioned along one edge as illustrated in Figure 19.

In one embodiment, elastic member 60 is positioned completely within the interior section 70. In other embodiments, elastic member 60 is positioned within the interior section 70 and extends outward from one or more sides.

A limiter may prevent movement of the sections 20, 30 beyond a predetermined amount. Figure 20 illustrates one embodiment having a rigid limiting member 90 positioned within the interior section 70. Inward movement of the sections 20, 30 causes

deformation of the elastic members 60a, 60b. At a predetermined amount of movement, a top edge of limiting member 90 contacts the section 20 and prevents further inward movement. Limiting member 90 may have a variety of different shapes and orientations. Another limiting embodiment is illustrated in Figures 21A and 21B. Sections 20, 30 are formed with ends 28, 38 positioned along the bases 24, 34 opposite from the intermediate section 40. In a first position as illustrated in Figure 21A, ends 28, 38 are spaced apart.

This allows for inward movement of the sections 20, 30 during vertebral movement. At a predetermined amount of inward movement, ends 28, 38 contact together as illustrated in Figure 21B and further inward movement is prevented.

In one embodiment, one or both sections 20, 30 are constructed to have increased contact with the vertebral members. In one embodiment, the sections 20, 30 are constructed of a porous material. In another embodiment, sections 20, 30 are textured. In still other embodiments, sections 20, 30 include spikes or serrations. In one embodiment, one or both sections 20, 30 may be coated with osteo-conductive material. Embodiments of the material may include hydroxyapatite and BMP.

In some embodiments as illustrated in Figures 1 and 11, one or more tethers 150 may further attach the device 10 to the spinous processes 102. In one embodiment, tethers 150 are attached to the arms 21, 22, 31, 32 and extend around the spinous process 102. Tether 150 may be constructed from materials that are elastic, semi-elastic, or inelastic. Tether 150 may be solid, such as constructed from silicone, may be braided or woven, such as a polyester braid or weave, or may be a combination of different materials and constructions.

Tethers 150 may also be used to provide additional resistance to device 10. In one embodiment as illustrated in the embodiments of Figures 23 and 24, tether 150 extends across the opening into the interior section 70. In one embodiment, tether 150 has a narrow width as illustrated in Figure 24. In another embodiment, tether 150 is wider, and may even extend across the entire width of the opening into the interior section 70. In one embodiment, a single tether 150 extends across the opening. In other embodiments as illustrated in Figure 26, multiple tethers 150 may extend across the opening.

Figure 25 illustrates an embodiment with the tether 150 extend around the intermediate section 40 and bases 24, 34. This tether 150 may be constructed of a single, continuous band, or multiple members connected together.

Tether 150 may function to contain the elastic member 60, and may also provide resistance during vertebral movement. In one embodiment, tether 150 is constructed of an elastic material that stretches upon movement of the vertebral members 100. In one embodiment, tether 150 is constructed of an inelastic material to prevent movement beyond a predetermined amount. In another embodiment, one or more tethers 150 are connected to the elastic member 60. In one embodiment, the tether 150 is completely contained within the elastic member 60. In one embodiment, tether 150 is positioned completely or in part on the exterior surface of the elastic member 60. In another embodiment, tether 150 extends outward from the elastic member 60. The tether or tethers 150 connected to the elastic member 60 may provide additional resistance during vertebral movement.

Vertebral movement may cause relative movement of the sections 20, 30. The terms “inward movement”, “outward movement”, and the like are used herein in a general sense to describe the general motion of the sections 20, 30 that reduces and enlarges the distance between the sections 20, 30. The sections 20, 30 may move directly towards one another during this movement, or there may be some lateral component to the movement. Further, the vertebral movement may cause movement of one or both of the sections 20, 30.

Spatially relative terms such as “under”, “below”, “lower”, “over”, “upper”, “lower”, “intermediate”, and the like, are used for ease of description to explain the relative positioning of elements. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as “first”, “second”, and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting. Like terms refer to like elements throughout the description.

As used herein, the terms “having”, “containing”, “including”, “comprising” and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles “a”, “an” and “the” are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention.

The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

Claims

What is claimed is:

1. An interspinous device positioned between first and second vertebral members, the device comprising:

an upper section sized to contact the first vertebral member;

a lower section sized to contact the second vertebral member; and

an intermediate section that connects the upper and lower sections and forms at least one of a posterior and anterior wall, the intermediate section having multiple turns that form an overlapping configuration;

an interior section formed between the upper section, the lower section, and the intermediate section, the interior section having an opening opposite from the intermediate section; and

an elastic member positioned within the interior section;

the intermediate section and elastic member being constructed to provide variable resistance to movement of the upper and lower sections.

2. The device of claim 1, wherein the intermediate section comprises both an anterior wall and a posterior wall.

3. The device of claim 1, wherein the intermediate section has multiple sections arranged in horizontal overlap.

4. The device of claim 1, wherein the intermediate section has multiple sections arranged in vertical and horizontal overlap.

5. The device of claim 1, wherein the upper section, the lower section, and the intermediate section are constructed from a single member.

6. The device of claim 1, wherein the intermediate section is positioned along a posterior edge of the upper and lower sections.

7. The device of claim 1, wherein the intermediate section is positioned along an anterior edge of the upper and lower sections.
8. The device of claim 1, wherein the intermediate section is constructed of first and second support members.
9. The device of claim 1, further comprising a tether that extends across an opening of the interior section.
10. The device of claim 1, further comprising a tether that extends around the interior section.
11. The device of claim 1, further comprising a tether connected to the elastic member.
12. An interspinous device positioned between first and second vertebral members, the device comprising:
 - an upper section sized to contact the first vertebral member;
 - a lower section sized to contact the second vertebral member; and
 - an intermediate section that connects the upper and lower sections and forms one of a posterior and anterior wall, the intermediate section having multiple turns that form an overlapping configuration;and
 - an elastic member positioned between the upper and lower sections;
 - the intermediate section and elastic member being constructed to provide variable resistance to movement of the upper and lower sections.
13. The device of claim 12, further comprising a second intermediate section spaced away from the intermediate section and forming an enclosed interior space between the upper and lower sections, the elastic member being positioned within the interior space.
14. The device of claim 13, wherein lateral sides of the interior space are open.

15. An interspinous device positioned between first and second vertebral members, the device comprising:

- an upper section sized to contact the first vertebral member;
- a lower section sized to contact the second vertebral member; and
- an intermediate section that connects the upper and lower sections, the intermediate section connecting together at least one of anterior and posterior ends of the upper and lower sections; and

- an elastic member positioned within a space formed between the upper and lower sections, the elastic member having a shape with an area that increases from an upper surface towards a lower surface to provide variable resistance to inward movement of the upper and lower sections.

16. The device of claim 15, wherein the upper surface is attached to the upper section and the lower surface is attached to the lower section.

17. The device of claim 15, wherein the upper surface is spaced away from the upper section when the device is in a neutral position.

18. The device of claim 15, wherein the elastic member has a height that changes from a posterior side to an anterior side.

19. The device of claim 15, further comprising a tether that extends between the upper and lower sections to provide resistance to movement of the vertebral members.

20. An interspinous device positioned between first and second vertebral members, the device comprising:

an elongated member having an overlapping configuration with an intermediate section that spaces apart upper and lower sections; and

first and second elastic members positioned between the upper and lower sections and proximate to the intermediate section, the elastic members sized to space apart the first and second endplates during movement of the vertebral members, wherein the first elastic member has a greater height than the second elastic member.

21. The device of claim 20, wherein the first and second elastic members have different stiffnesses.

22. The device of claim 20, wherein the first elastic member is connected to the second elastic member.

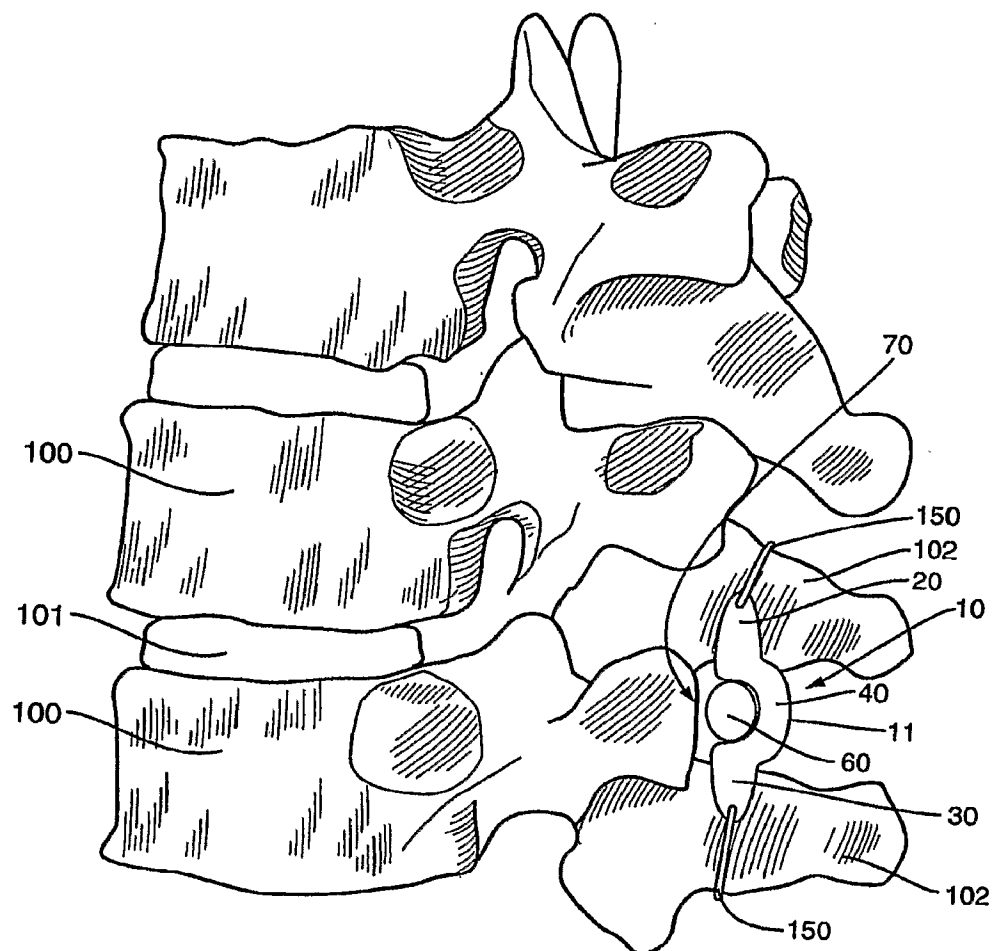
23. The device of claim 20, wherein the first elastic member is contained within the second elastic member.

24. The device of claim 20, further comprising a tether that extends across an opening into the intermediate section.

25. An interspinous device positioned between first and second vertebral members, the device comprising:

- an upper section sized to contact the first vertebral member;
 - a lower section sized to contact the second vertebral member;
 - a first intermediate section extending between anterior sections of the upper and lower sections;
 - a second intermediate section extending between posterior sections of the upper and lower sections;
 - an interior section formed between the first and second intermediate sections; and
 - an elastic member positioned within the interior section;
- the first and second intermediate sections and the elastic member providing resistance to movement of the vertebral members.

26. The device of claim 25, wherein the interior section has open lateral sides.

**FIG. 1**

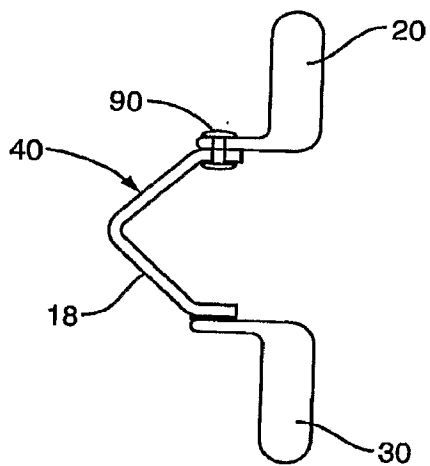


FIG. 2

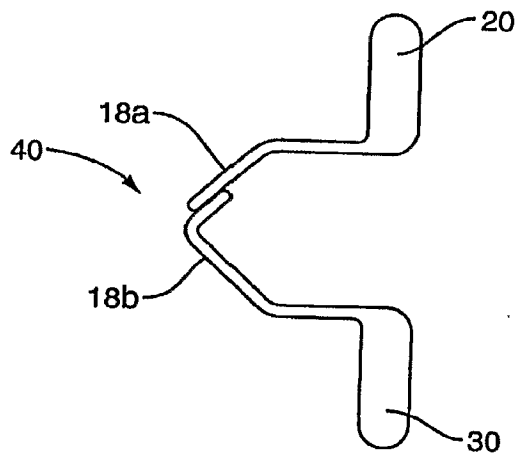


FIG. 3

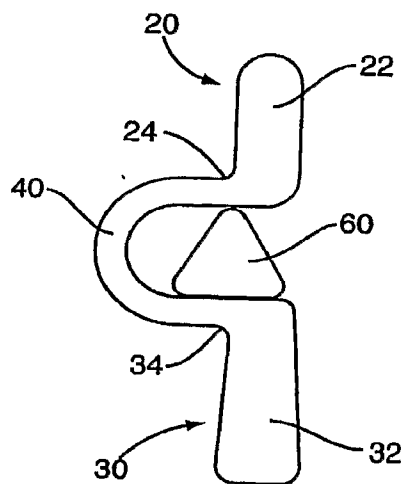


FIG. 4

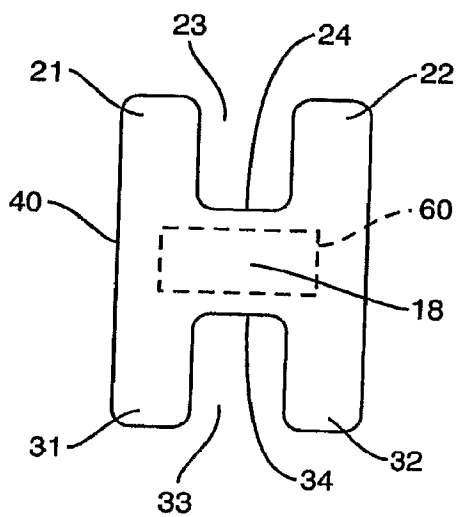
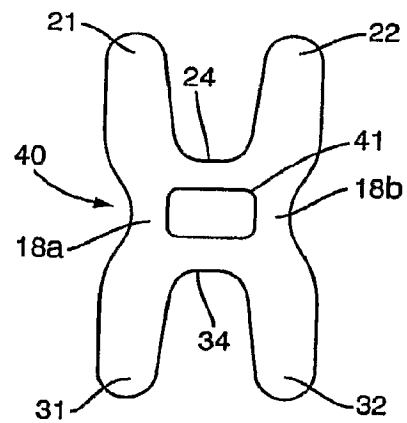
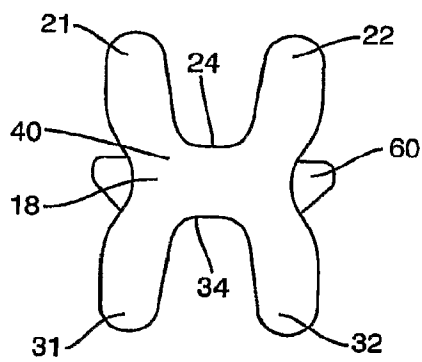
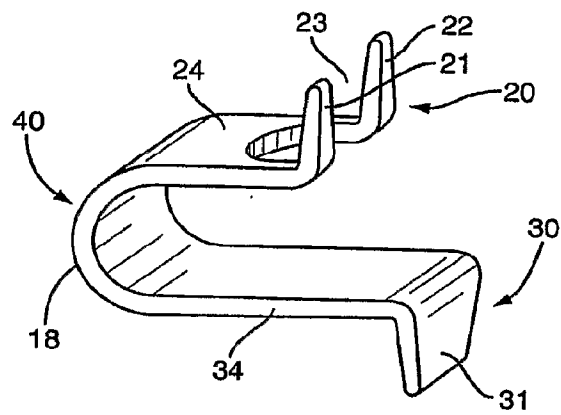
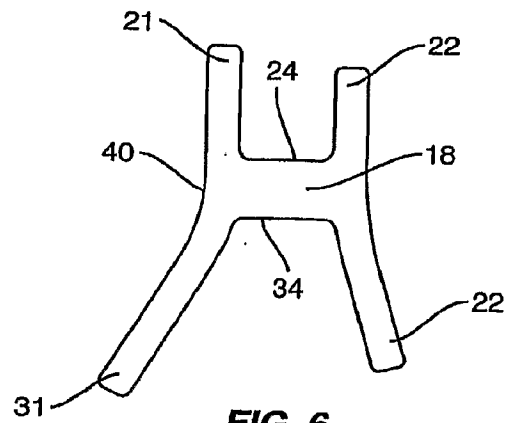


FIG. 5



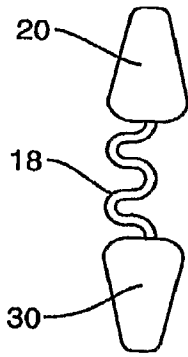


FIG. 10A

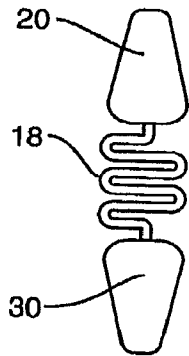


FIG. 10B

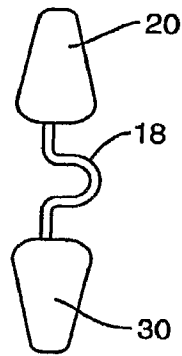


FIG. 10C

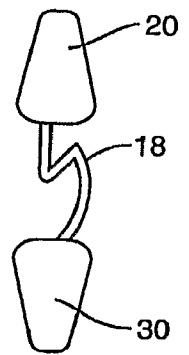


FIG. 10D

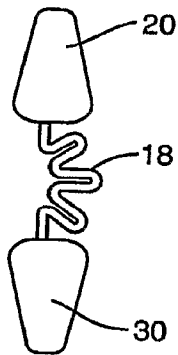


FIG. 10E

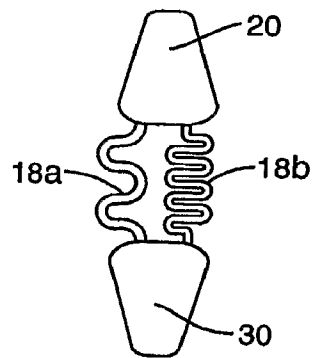
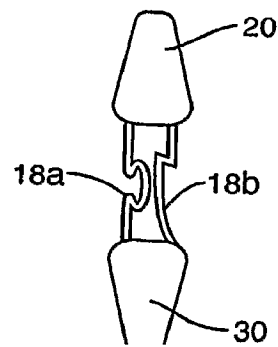
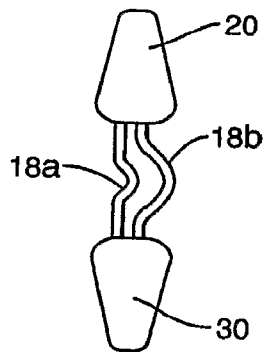


FIG. 10F



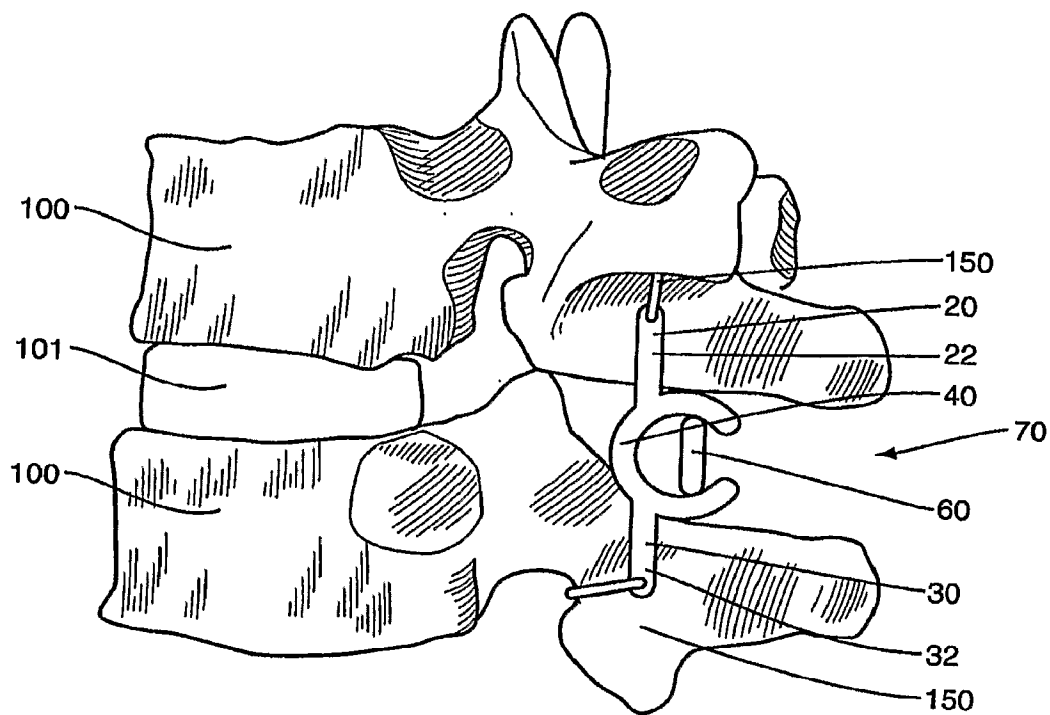
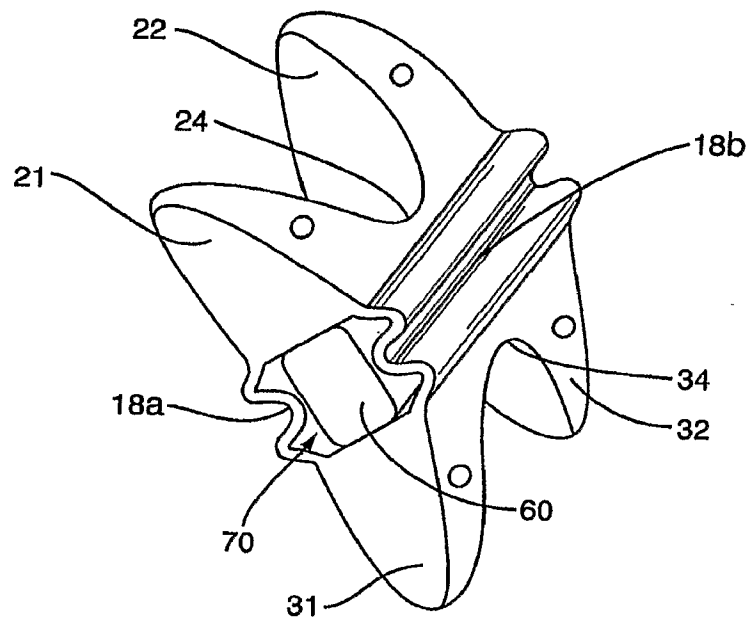
**FIG. 11**

FIG. 12

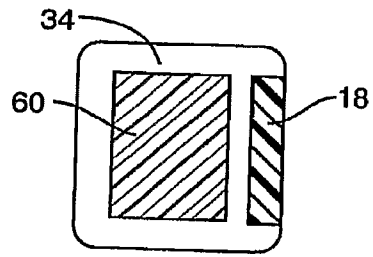


FIG. 13A

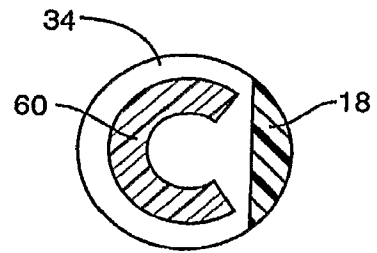


FIG. 13B

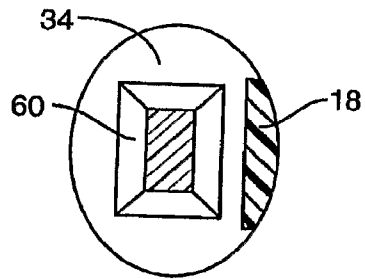


FIG. 13C

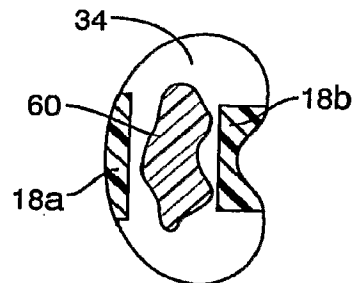


FIG. 13D

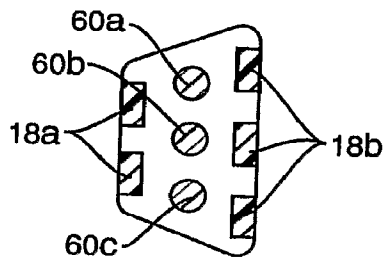


FIG. 13E

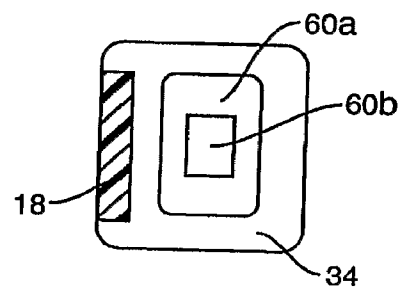


FIG. 13F

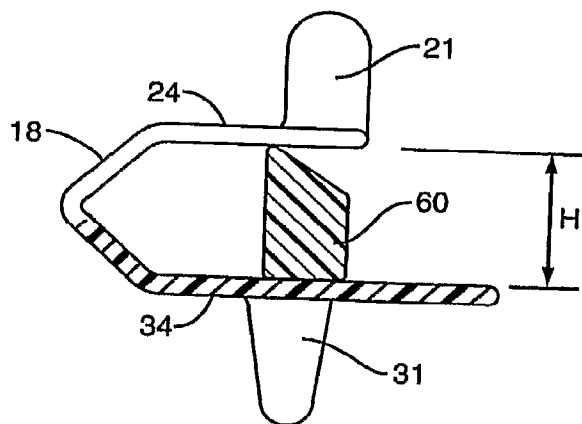


FIG. 14

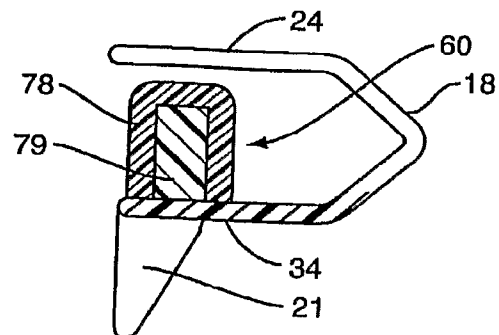


FIG. 17

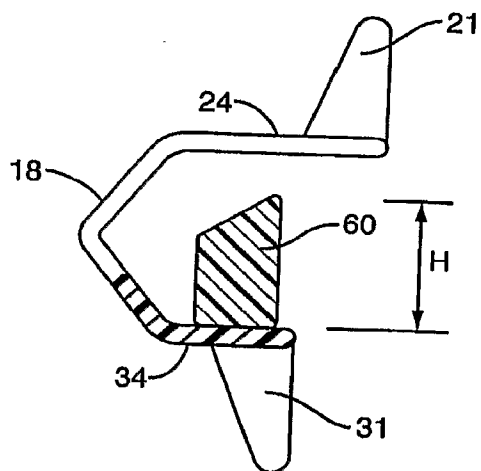


FIG. 15

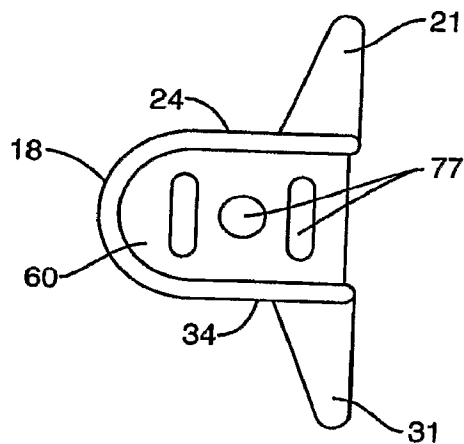
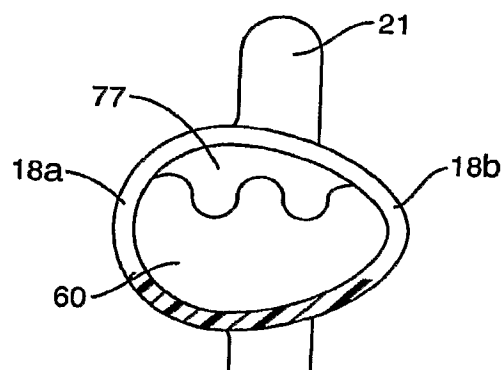
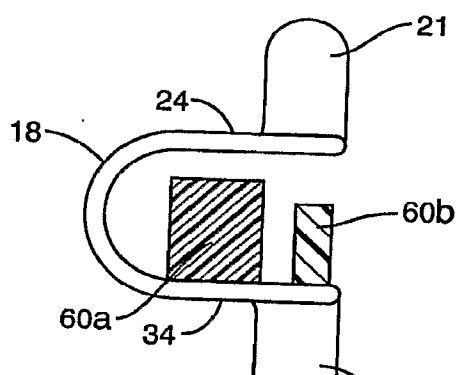


FIG. 18



8/9

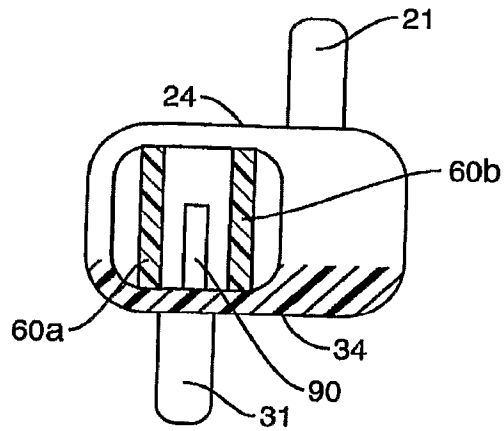


FIG. 20

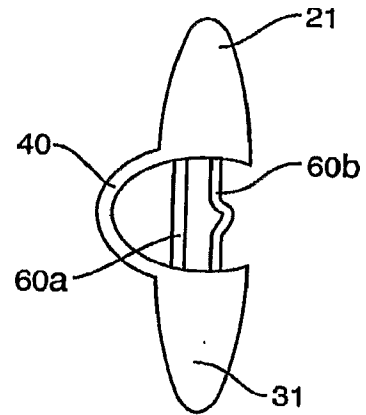


FIG. 22A

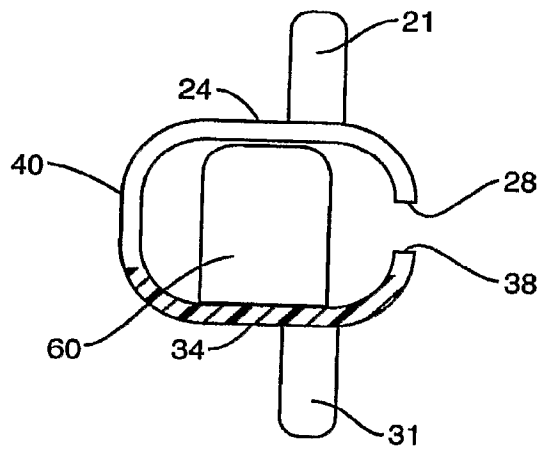


FIG. 21A

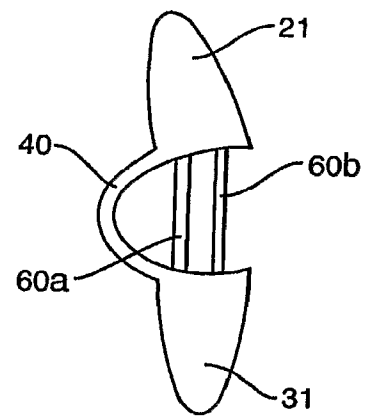
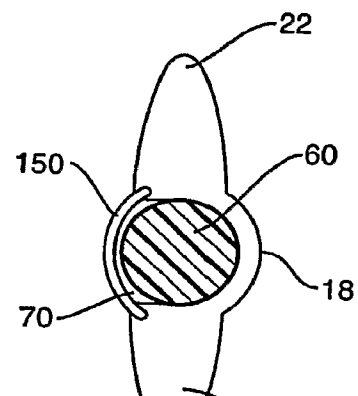
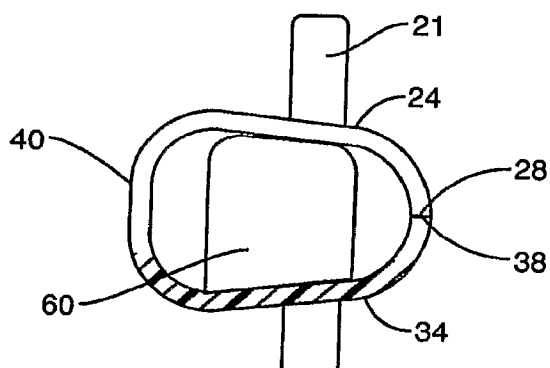


FIG. 22B



9/9

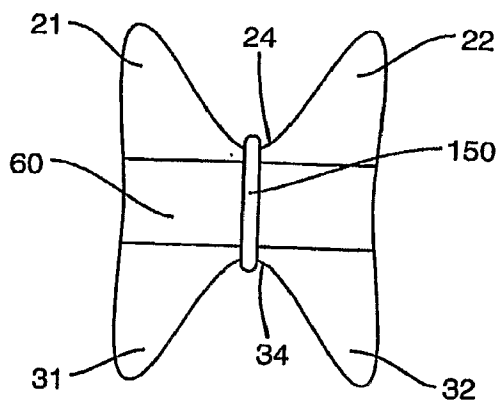


FIG. 24

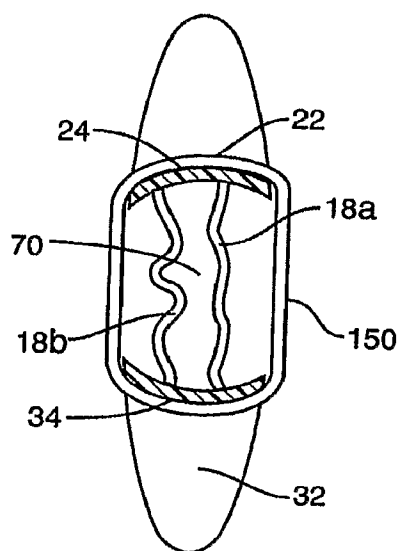
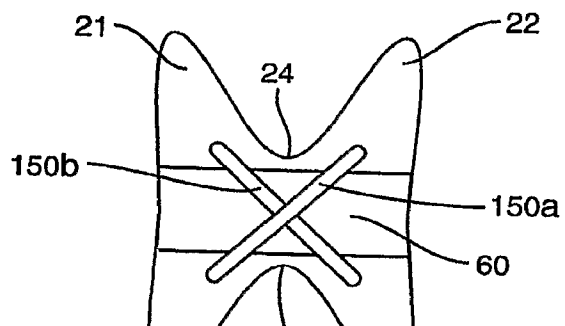


FIG. 25



INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/060905

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|----------------------------|
| A | FR 2 722 980 A1 (SAMANI JACQUES [FR]) 2 February 1996 (1996-02-02) abstract; claims 1-3; figure 5 page 7, line 32 - page 8, line 3 ----- | 1-15, 20, 25 |
| A | FR 2 774 581 A1 (DIMSO SA [FR]) 13 August 1999 (1999-08-13) abstract; claims 1,2,11,13; figures 2,4,7 ----- | 1, 12, 15, 20 25, 26 |
| X | | |
| P, A | WO 2006/106246 A (SPINEVISION [FR]; ATTIA DAVID [FR]; DROULOUT THOMAS [FR]; PETIT DOMINI) 12 October 2006 (2006-10-12) abstract; figures 1,3,5 ----- | 1, 12, 15, 20, 25 |
| A | US 2003/191470 A1 (RITLAND STEPHEN [US]) 9 October 2003 (2003-10-09) abstract; figures 19,10 ----- | 1, 12 |

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

23 May 2007

Date of mailing of the international search report

01/06/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Macaire, Stéphane

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/060905

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|----|---------------------|----------------------------|---------------------|
| FR 2722980 | A1 | 02-02-1996 | JP 3631293 B2 | 23-03-2005 |
| | | | JP 8052166 A | 27-02-1996 |
| | | | US 5645599 A | 08-07-1997 |
| FR 2774581 | A1 | 13-08-1999 | AT 303104 T | 15-09-2005 |
| | | | AU 2428399 A | 30-08-1999 |
| | | | CA 2320821 A1 | 19-08-1999 |
| | | | DE 69926995 D1 | 06-10-2005 |
| | | | DE 1054638 T1 | 03-05-2001 |
| | | | EP 1054638 A1 | 29-11-2000 |
| | | | ES 2151876 T1 | 16-01-2001 |
| | | | WO 9940866 A1 | 19-08-1999 |
| | | | JP 2002502662 T | 29-01-2002 |
| | | | US 6440169 B1 | 27-08-2002 |
| WO 2006106246 | A | 12-10-2006 | FR 2884136 A1 | 13-10-2006 |
| US 2003191470 | A1 | 09-10-2003 | US 2006009768 A1 | 12-01-2006 |